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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,138	08/30/2001	Wallace K. Dyer	04118-0104 (43076-250892)	9300

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[REDACTED] EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
1639	8

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>F/k/cn/</i>	Application No.	Applicant(s)
	09/943,138	DYER, WALLACE K.
	Examiner	Art Unit
	Jon D Epperson	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) 5,6 and 12-19 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 and 7-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on May 8, 2003 (Paper No. 7).

Status of the Claims

2. Claims 1-19 are pending in the present application. Applicants amended claims 1-5 and 7-17 in Paper No. 3.

3. Applicant's response to the Restriction and/or Election of Species requirements in Paper No. 7 is acknowledged (i.e., Applicants reaffirmed the election of Group I, claims 1-14) and claims 15-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see below i.e., Response to Restriction and/or Election of Species).

4. Please note: Applicant's elected species (polyvinylpyrrolidone, facial tissue, 125 µm, K =17) was found in the art. Applicant's *specifically* elected species (biocompatible micronized polyethylene) was searched and was not found in the prior art. Thus, the search was expanded to

non-elected species, which *were* found in the prior art, see rejections below. Applicant is reminded of MPEP § 803.02 with respect to species elections:

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. *The prior art search, however, will not be extended unnecessarily to cover all nonelected species.* Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

5. Claims 5-6 and 12-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species, the requirement having been traversed in Paper No. 6 (see below i.e., **Response to Restriction and/or Election of Species**).

6. Therefore, claims 1-4 and 7-11 are examined on the merits in this action.

Response to Restriction and/or Election of Species

7. Applicant's election of Group I (claims 1-14) reaffirmed in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

8. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

9. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, “the list may not be incorporated into the specification but must be submitted in a separate paper.” Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.
10. The references listed on applicant’s PTO-1449 form have been considered by the Examiner. A copy of the form is attached to this Office Action.

Specification

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant’s cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims Rejections - 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-4 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. In new claim 1 (introduced in the Preliminary Amendment), the phrase “wherein the solid polymer particles are mechanically stable and are suspended in a liquid carrier substrate” represents new matter because the specification discloses stability for the entire composition (no just the particles) and does not disclose a “suspension” of particles in a liquid phase. With regard to Applicant’s remarks (see Paper No. 3, page 5), the indicated pages do not remedy the deficiencies in the specification mentioned above. Therefore, claim 1 and all dependent claims are rejected as new matter.

It is noted that an amendment filed along with the filing of an application (as in the present Preliminary Amendment) does not enjoy the status as part of the original disclosure in an application filed under 37 CFR 1.53(b) unless it is specifically referred to in the oath or declaration filed therewith (e.g., see MPEP 608.04b). In the present instance, the oath or declaration fails to specifically refer to the Preliminary Amendment in its “reviewed and understands” clause (which is lacking); nor does the present declaration indicate that a CIP was intended to be filed by applicant.

13. Claims 1-4 and 7-11 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 USC 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a written description rejection.

These claims encompass a broad genus. For example, claim 1 discloses "solid polymer particles that are mechanically stable." The scope of this claim includes an infinite number of structural variants (i.e., solid polymer particles) wherein no distinguishing structural attributes are provided for these polymer particles. The specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form the solid polymer particles. Although the specification discloses many possible solid polymer particles (see claims 2-3), the specification and claims do not provide any guidance as to what structural features all of these solid polymer particles share. Consequently, it is not possible to determine *a priori* which solid polymer particles would be "mechanically stable" in the body and which would not be because there is no common structural attributes that can link together all of these different solid polymer particles i.e., there is no teaching that would allow a person of skill in the art to determine *a priori* all the different types of solid polymer particles that should be included in this genus from the few examples provide by applicants.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails

to describe the common attributes or characteristics that identify all of the members of the genus or even a substantial portion thereof, and because the genus is enormous and highly variant, listing examples e-PTFE (see specification, claim 2) is insufficient to teach the entire genus. Consequently, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe this enormous genus. Thus, applicant was not in possession of the claimed genus.

14. Claims 1-4 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for solid polymer particles that are larger than 60 μm (see specification, Example 30), does not reasonably provide enablement for solid polymer particles that are less than 60 μm . Consequently, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these broad claims. This is an enablement rejection.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. Some of these factors may include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: These claims are broad because they are drawn to any “solid polymer particles”, which reads on an infinite number of possibilities. Furthermore, the nature of the invention cannot be fully determined because the materials that are encompassed by these broad claims has not been disclosed.

(3 and 5) The state of the prior art and the level of predictability in the art: The prior art states that biphasic injectable compositions DO NOT WORK for small particle sizes (~60 μm) because the small particles are engulfed by macrophages (see Ersek et al, 1991 Reference, IDS Paper No. 2).

(4) The level of one of ordinary skill: The level of skill required would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicant’s specification also states that small particle sized do not work (see page 12, paragraph 2).

(8) The quantity of experimentation needed to make or use the invention base on the content of the disclosure: It is clear from the literature and Applicant’s specification that small particle sizes do not work and Applicant’s specification has not provided any guidance that would render a person of skill in the art with the knowledge and/or tools to remedy the problem. There must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an

unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For *claims 1 and 7*, the term “liquid carrier substrate” is vague and indefinite.

For example, it is not clear how the term “carrier” further defines the term liquid?

Wouldn’t every liquid be considered a “carrier” if you place something in it. If so, how does the term “carrier” further limit the term liquid in this case since something is being placed in the liquid i.e., could you have a situation wherein you place something in the liquid and have that liquid not considered to be a carrier? Furthermore, is the term “substrate” further defining the liquid or is it further defining what is placed in the liquid (i.e., the solid polymer particles)? If the term substrate does further define the liquid or particles then what qualities or limitations does the term impart on said liquid or

particles? Applicants are requested to clarify. Therefore, claims 1, 7 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-4 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al (Ersek, R. A.; Gregory, S. R.; Salisbury, A. V. "Bioplastique at 6 Years: Clinical Outcome Studies" *Plast. Reconstr. Surg.* November 1997, 100(6), 1570-1574) (IDS Paper No. 2) as evidenced by Ersek et al (Ersek, R. A.; Beisang, A. A. "Bioplastique: A New Textured Copolymer Microparticle Promises Permanence in Soft-Tissue Augmentation" *Plast. Reconstr. Surg.* 1991 87, 693-702) (IDS Paper No. 2), the National Honey Board (<http://www.nhb.org/foodtech/tgloss.html>) and Polymer Products from Aldrich and in further view of Applicant's specification to demonstrate inherency. Please note that MPEP 2131.01(d) permits the citation of references or evidence in an anticipation rejection under 35 U.S.C. § 102 in order to show that a characteristic not disclosed in the reference is inherent.

For *claims 1-4*, Ersek et al (see entire document) discloses a biphasic polymer for augmentation of soft tissue, which anticipates claim 1. For example, Ersek et al

discloses “bioplastique” as the biphasic injectable composition comprising mechanically stable solid polymer particles suspended in a “polyvinylpyrrolidone” liquid carrier substrate (see Ersek et al, abstract; see also Background, column 1, paragraph 1, “Bioplastique is a trade name given to a mixture of low molecular weight polyvinylpyrrolidone and solid polymer particles of greater than 100 microns in diameter ... material is ... injected ... for permanent augmentation ... areas such as the face”; please note that polyvinylpyrrolidone is Applicant’s elected species for the liquid carrier substrate). Ersek et al does not disclose what the mechanically stable solid polymer particles of bioplastique are made of; however, Ersek et al does state that the material is the same as that set forth in his earlier 1991 reference that does disclose the identity of the stable solid polymer particles (see Ersek et al, 1997 reference, page 986, column 2, last paragraph, “This material [i.e., the solid polymer particles] is the same as that described for initial animal experimentation [i.e., referring to the 1991 Ersek et al reference]”). Thus the Examiner contends that Bioplastique as set forth by the 1997 Ersek et al reference is inherently made from fully polymerized and vulcanized methyl-methylpolysiloxane $[(\text{CH}_2)_2-\text{SiO}]$ as the solid polymer particles with a size between 100 and 600 μm as disclosed by the 1991 Ersek et al reference (see Ersek et al, 1991 reference, Materials and Methods Section; see also Applicant’s specification, Bioplastique section, page 6, line 31) (Note that these materials fall within the scope of “long chain aliphatic polymers”).

For *claims 8-11*, Ersek et al does not disclose the K value for the Bioplastique, however, a K value between 13-19 is an inherent property of the material used. For

example, Applicant's specification states that the PVP used has a molecular weight of around 15,000-30,000 and has a viscosity similar to that of Honey. Furthermore, the National Honey Board (see <http://www.nhb.org/foodtech/tgloss.html>) states that honey has a viscosity around 20.4 poise to 138 poise depending on the water condition and between 2.6 and 600 poise depending on the temperature. The relationship between the K-value and the molecular weigh and/or intrinsic viscosity of PVP has been calculated and clearly shows that that the K value for the Bioplastique is in the range of 13-19 (see Applicant's specification, page 6, lines 17-18; see also National Honey board Reference, page 12; see also Polymer Products from Aldrich Reference, page 5, Table 3 citing "GAF(ISP) Technical Bulletin 2302-203 SM-1290, "PVP polyvinylpyrrolidone Polymers", 1990; see especially Table 3, line 1 wherein the viscosity is 7(2) cSt, K value is 13-19 and Molecular weight is ~12,000).

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

17. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bley (EP 0 730 847 A1) (Date of Patent is 7/3/1995).

For *claims 1-4*, Bley (see entire document) discloses “[a] physiologically acceptable composition comprising a plurality of physiologically acceptable solid polymer particles dispersed in a physiologically acceptable biodissipatable liquid carrier ... and [the solid polymer particles] being substantially insoluble in the liquid carrier and in body fluids (see Bley, claim 1), which anticipates claims 1-4. Bley goes on to disclose a variety of hydrophilic and hydrophobic solid polymers and liquid carriers (see claims 2-9; see also columns 6-8) that fall within the scope of Applicants invention.

18. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Freed (U.S. Patent No. 5,480,644) (Date of Patent is **January 2, 1996**).

For *claims 1-4*, Freed (see entire document) discloses an injectable biomaterial for repairing muscles that anticipated claims 1-4. For example, Freed discloses “polytetrafluoroethylene” beads (see Freed, column 4, paragraph 2, “The biomaterial used in the invention may be selected from a number of sources; however, it must be injectable, biocompatible, essentially non-immunogenic, and persist at the site of placement for at least three months. Alternatively the biomaterial may be an “aqueous suspension” of a biopolymer with a biocompatible fluid lubricant to improve the intrusion of the biopolymer into the tissue ... Fluid lubricants may include: hyaluronic acid ... fatty acids ... Biopolymers may include: ... polytetrafluoroethylene beads”).

Contact Information

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.

July 11, 2003



ANDREW WANG
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